K081342 (pg 1/1)

II. SUMMARY AND CERTIFICATION

AUG 13 2008

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Joshua Clarin
11400 73rd Avenue North
Maple Grove, MN 55369
Ph: 612-644-8402
Fax: 763-488-3350

Date Prepared: May 12, 2008

Trade Name: Reprocessed External Fixation device

Classification Name: Single/multiple component metallic bone fixation appliances and accessories.

Classification Number: Class II, 21 CFR 888.3030

Product Code: KTT

Predicate Devices:	The reprocessed external fixation device is substantially equivalent to the Smith & Nephew Jet-X® External Fixation System.
Device Description:	SterilMed's reprocessed external fixation devices consists of the standard bridge elements (rods, articulating and telescoping components), and connection elements (clamps) contained in the original manufacturer's system. Some of the components are MR safe and made of non-magnetic materials. MR safe components are intended for use in the MR environment. Note: Only the non-patient contact, external frame elements are the subject of this submission, the anchorage pins and wire elements are not included in the scope of this submission
Intended Use:	The reprocessed fixation device is indicated for use with adults and pediatric patients and intended for fracture fixation (open and closed) fractures and disease generally resulting in joint contractures or loss of range and fractures requiring distraction; post-traumatic joint contracture which has resulted in loss of range of motion; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; joint arthrodesis; correction of segmental bony or soft tissues; and management of comminuted intra-articular fractures of the distal radius.
Functional and Safety Testing:	Representative samples of reprocessed external fixation constructs were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning procedure. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Conclusion:	The Reprocessed External Fixation Devices are substantially equivalent to the Smith & Nephew Jet-X® external fixation devices. This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SterilMed, Inc.
% Mr. Joshua Clarin
Sr. Regulatory Affairs Specialist
11400 73rd Avenue North
Maple Grove, Minnesota 55369

AUG 13 2008

Re: K081342
Trade/Device Name: Reprocessed External Fixation Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: July 16, 2008
Received: July 18, 2008

Dear Mr. Clarin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081342 (pg 1/1)

Device Name: Reprocessed External Fixation Device

Indications for Use:
The reprocessed fixation device is indicated for use with adults and pediatric patients and intended for fracture fixation (open and closed) fractures and disease generally resulting in joint contractures or loss of range and fractures requiring distraction; post-traumatic joint contracture which has resulted in loss of range of motion; pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; joint arthrodesis; correction of segmental bony or soft tissues; and management of comminuted intra-articular fractures of the distal radius.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Courtney Buehler for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081342